

### **REMARKS**

These remarks are in response to the Final Office Action mailed September 29, 2009. Claims 11-18, 20-48, 65-80 and 89-93 have been cancelled as directed to a non-elected invention. Claims 79, 81-88, 97 and 107 have been cancelled without prejudice to Applicants' right to prosecute the cancelled subject matter in any divisional, continuation, continuation-in-part or other application.

Applicants respectfully thank Examiner Dunston for the courteous telephonic interview conducted with Applicants' representative, Joseph R. Baker, Jr., on January 29, 2010. During the Interview amendments and remarks were considered to overcome the pending rejections.

Claim 49 has been amended as suggested by the Examiner during the telephonic interview. Applicants respectfully request rejoinder of claim 50 and 99 which are set forth in proper dependent format.

No new matter is believed to have been introduced.

#### **I. CLAIM OBJECTIONS**

Claim 49 is objected to for a misspelling of "multivariate". The term has been deleted, thus the objection is moot.

Claim 99 stands objected to as allegedly directed to a non-elected invention. Applicants respectfully request rejoinder of claim 99 and claim 50, both of which are in proper dependent format.

#### **II. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH**

Claims 49, 51-55, 57, 61-64, 96-107 stand rejected under 35 U.S.C. §112, first paragraph, because, while being enabling for (A) a method for assessing the risk of colorectal polyps and colorectal cancer in a subject, comprising (i) obtaining a biological colorectal sample from the subject; (ii) isolating cellular RNA from the sample; (iii) amplifying and quantifying RNA expression levels for SEQ ID NO:s 1 and 2; (iv) comparing the quantified expression levels of SEQ ID NOs: 1 and 2 in normal control colorectal samples; and (v) determining an increased risk of colorectal polyps and colorectal cancer in the subject when at least one of SEQ ID NOs: 1 and 2 is increased in expression in the sample from the subject as compared to the normal

control, allegedly does not provide enablement for using the method for determination of colorectal polyps and colorectal cancer (i.e., diagnosis), or management of colorectal polyps and colorectal cancer, which includes estimating risk, early diagnosis, establishing prognosis, monitoring patient treatment or detecting relapse; using any normal control sample as a comparison; using any change in expression levels to determine risk; using biomarkers selected from SEQ ID NOs: 5, 15, and 16. Applicants respectfully traverse this rejection.

The claims have been amended consistent with the Examiner's suggestion in the telephonic interview and with the indicated scope of enablement above. Accordingly, Applicants respectfully request withdrawal of the rejection.

Claims 79 and 81-88 stand rejected as allegedly containing new matter. Applicants respectfully disagree; however the rejection is moot with respect to these claims.

### **III. REJECTION UNDER 35 U.S.C. §103**

Claims 79, 81-87 stand rejected under 35 U.S.C. §103 as allegedly unpatentable over Baker et al. in view of Gould et al., Goltry et al., GenBank Accession No. M23698, Buck et al., and Ahern et al. Applicants respectfully disagree; however the rejection is moot.

For at least the foregoing, the Applicant submits that the claimed invention is patentable and request reconsideration and notice of such allowable subject matter.

The Director is authorized to charge any required fee or credit any overpayment to Deposit Account Number 50-4586, please reference the attorney docket number above.

The Examiner is invited to contact the undersigned at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

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